Preliminary Amendment Serial No. (PCT/GB2004/003329)

Filed: (30 July 2004)

IN THE CLAIMS:

1. (Currently Amended) An oral drug delivery system which comprises a biliquid foam comprising:

from 1 to 20% by weight of a continuous hydrophilic phase,

from 70 to 98% by weight of a pharmaceutically acceptable oil which forms a discontinuous phase, the said pharmaceutically acceptable oil having dissolved or dispersed therein a poorly water-soluble drug in an amount of from 0.1 to 20% by weight, said poorly water-soluble drug dissolving in water in an amount of less than 1% by weight, and the biliquid foam including therein from 0.5 to 10% by weight of a surfactant to enable the formation of a stable biliquid foam, all percentages being based upon the total weight of the formulation.

- 2. (Original) An oral drug delivery system as claimed in claim 1 wherein the continuous hydrophilic phase is an aqueous phase.
- 3. (Original) An oral drug delivery system as claimed in claim 2 wherein the aqueous phase is water.
- 4. (Original) An oral drug delivery system as claimed in claim 2 wherein the aqueous phase incorporates a salt or a co-solvent therein.
- 5. (Original) An oral drug delivery system as claimed in claim 1 wherein the continuous hydrophilic phase is a non-aqueous solvent.
- 6. (Original) An oral drug delivery system as claimed in claim 5 wherein the non-aqueous solvent is an aliphatic alcohol, polyethylene glycol, propylene glycol or glycerol, or mixtures thereof.

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7. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the pharmaceutically acceptable oil is a mono-, di- or triglyceride, or a mixture thereof.

- 8. (Original) An oral drug delivery system as claimed in claim 7 wherein the mono-, di- or triglycerides are the glycerol esters of fatty acids containing from 6 to 22 carbon atoms.
- 9. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the surfactant comprises an alkyl polyglycol ether, an alkyl polyglycol ester, an ethoxylated alcohol, a polyoxyethylene sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, a polyoxyethylene fatty acid ester, an ionic or non-ionic surfactant, a hydrogenated caster oil/polyoxyethylene glycol adduct containing from 25 to 60 ethoxy groups, a castor oil/polyoxyethylene glycol adduct containing from 25 to 45 ethoxy groups, or mixtures thereof.
- 10. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 which includes therein a coemulsifier in an amount sufficient to complete the solubilization of the poorly water-soluble drug.
- 11. (Original) An oral drug delivery system as claimed in claim 10 wherein the co-emulsifier is a phosphoglyceride or a phospholipid.
- 12. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the discontinuous phase comprises from 85 to 96% by weight of the biliquid foam.

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13. (Original) An oral drug delivery system as claimed in claim 12 wherein the discontinuous phase comprises from 90 to 95% by weight of the biliquid foam.

- 14. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the continuous hydrophilic phase comprises from 2 to 10% by weight of the biliquid foam.
- 15. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the surfactant comprises from 0.5 to 5% by weight of the composition.
- 16. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 wherein the poorly water-soluble drug is an analgesic or anti-inflammatory agent, an anthelmintic, an anti-arrhythmic agent, an anti-coagulant, an anti-depressant, an anti-diabetic, an anti-epileptic, an anti-fungal agent, an anti-gout agent, an anti-hypertension agent, an anti-malarial, an anti-migraine agent, an anti-muscarinic agent, an anti-neoplastic agent, an anti-protozoal agent, an anti-thyroid agent, an anxiolytic, sedative, hypnotic or neuroleptic agent, a corticosteroid, a dieuretic, an anti-Parkinsonian agent, a gastro-intestinal agent, a histamine H-receptor antagonist, a lipid regulating agent, an anti-anginal agent, a nutritional agent, an opiod analgesic, a sex hormone, a stimulant, or a therapeutic mixture thereof.

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17. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 which is in a unit dosage form.

- 18. (Original) An oral drug delivery system as claimed in claim 17 wherein the unit dosage form comprises capsules filled with the biliquid foam.
- 19. (Original) An oral drug delivery system as claimed in claim 18 wherein the capsules are hard or soft gelatin capsules.
- 20. (Currently Amended) An oral drug delivery system as claimed in any one of claims 1 to 16 claim 1 which is in the form of a dilutable concentrate.
- 21. (Original) An oral drug delivery system as claimed in claim 20 which is infinitely dilutable in a co-solvent.
- 22. (Currently Amended) An oral drug delivery system as claimed in any one of the preceding claims claim 1 for use in a method of treatment by oral administration to the human or animal body.